Study protocol

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Impact of Wait Times for Treatment on Clinical Outcomes in Patients with Obstructive Sleep Apnea: Protocol for a Randomized Control Trial.

Christina S. Thornton¹, Marcus Povitz¹,², Willis H. Tsai¹,²,³, Andrea H. Loewen¹,², Ada Ip-Buting³, Tetyana Kendzerska⁴, W. Ward Flemons¹,²,³, Kristin L. Fraser¹,², Patrick J. Hanly¹,²,³, and Sachin R. Pendharkar¹,²,³

¹Department of Medicine, Cumming School of Medicine, University of Calgary, Calgary, Canada
²Sleep Centre, Foothills Medical Centre, University of Calgary, Calgary, Canada
³Department of Community Health Sciences, Cumming School of Medicine, University of Calgary, Calgary, Canada
⁴Department of Medicine, Faculty of Medicine, University of Ottawa and Clinical Epidemiology Program, Ottawa Hospital Research Institute, 1053 Carling Avenue, Ottawa, Ontario, K1Y 4E9, Canada

Corresponding Author
Sachin R. Pendharkar, TRW Building, Rm 3E23, 3280 Hospital Drive NW, Calgary, AB, T2N 4Z6
Tel: 403-210-3904
Email: Sachin.pendharkar@ucalgary.ca

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Abstract

Background: Obstructive sleep apnea (OSA) is a common chronic condition that is associated with significant morbidity and economic cost. Prolonged wait times are increasingly being recognised as a barrier to diagnosis and treatment of many chronic diseases; however, no study to date has prospectively evaluated the impact of wait times on health outcomes in OSA.

Objective: The purpose of this study is to determine whether treatment outcomes for individuals with OSA differ between patients managed using an expedited versus standard pathway.

Methods: A pragmatic randomized control trial design will be used with a target sample size of 200 adults. Participants with clinically significant uncomplicated OSA will be recruited through referrals to a large tertiary care sleep centre (Calgary, Alberta, Canada) and randomized to either early management (within 1 month) or usual care (approximately 6 months) with a 1:1 allocation using a concealed computer-generated randomization sequence. The primary outcome will be adherence to positive airway pressure (PAP) therapy at three months after treatment initiation. Secondary outcomes will include change in sleepiness, quality of life, patient satisfaction, and patient engagement with therapy from baseline to 3 months after PAP initiation, measured using validated questionnaires and qualitative methods.

Anticipated Results: This study will determine whether expedited care for OSA leads to differences in PAP adherence and/or patient-reported outcomes. More broadly, the findings of this study may improve the understanding of how wait time reductions impact health outcomes for other chronic diseases.

Key words: Obstructive sleep apnea; access to health care; time to treatment; treatment adherence; quality of care
**Introduction**

**Background:**

Obstructive sleep apnea (OSA) is a highly prevalent chronic condition with significant medical burden on both an individual and population level. Globally, the estimated prevalence of OSA, as defined by an apnea-hypopnea index (AHI) of ≥5 events per hour, is nearly one billion individuals [1]. The number of individuals with moderate to severe OSA, for whom treatment is recommended, is estimated to be over 400 million [1]. OSA is associated with poorer quality of life, increased cardiometabolic risk, more frequent motor vehicle collisions, and greater and more costly use of the healthcare system [2-5]. The annual cost of diagnosing and treating OSA is approximately USD $12.4 billion with the estimated economic cost of untreated OSA of USD $150 billion per year [6].

Treatment of OSA improves health outcomes and is cost-effective [7, 8]. However, there are barriers to effective diagnosis and treatment including under-recognition [9-12], variability in provider knowledge and supply-demand imbalance leading to long delays for care [13-15]. Based on expert opinion, Canadian clinical practice guidelines recommend a maximum wait time of six months for investigation of suspected OSA, [16] and the American Academy of Sleep Medicine has suggested that severity should be confirmed within two months of initial evaluation [17]. However, wait times far exceeding these recommendations are reported in many jurisdictions [8, 14, 15], highlighting the importance of alternative approaches to diagnosis and treatment initiation.

Currently, there is sparse literature describing the clinical impacts of reducing wait times for OSA care. In a single randomized trial, immediate polysomnography (PSG) compared to PSG after six months was associated with greater improvements in symptoms and quality of life at six months, and was cost-effective [18]. A notable limitation was that patients who were randomized to PSG at six months did not have PAP treatment whereas those in the earlier group did, calling into question whether results were due to therapy alone. In a post hoc analysis from a randomized trial of respiratory therapist management of severe sleep-disordered breathing, our group demonstrated that more timely initiation of positive airway pressure (PAP) therapy was associated with greater adherence to therapy [19]. This finding suggests that delayed care may change patient perceptions about the importance of sleep-disordered breathing, modify patient behavior (use of PAP), and result in poorer health outcomes. However, our study only included patients with severe sleep-disordered breathing (including sleep
hypoventilation); further confirmation is required in a more representative sample of uncomplicated patients with OSA.

**Study Objectives:**

The primary objective of this study is to evaluate the effect of more timely care for OSA on adherence to PAP therapy three months after treatment initiation. Secondary objectives are to determine if earlier care improves the treatment effect of PAP on patient reported sleepiness, quality of life and patient satisfaction. We will evaluate how expedited care impacts patient engagement in therapy by assessing initial acceptance of PAP therapy, patient activation and self-efficacy with respect to OSA treatment. Finally, we will conduct focus groups with patients to explore their perspectives on the relationship between wait times and treatment adherence.

**Methods**

**Study Design:**

The proposed study is a pragmatic randomized trial in which patients with OSA diagnosed using home sleep apnea testing (HSAT) will be randomized to either an early management strategy (clinical assessment within 1 month of HSAT) or usual care (clinical assessment approximately 6 months after HSAT) (Figure 1). This study is registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) with identifier numbers NCT04613414.

**Study Setting:**

The study will be conducted at the Foothills Medical Centre (FMC) Sleep Centre, a publicly funded, tertiary academic sleep centre in Calgary, Alberta, Canada with a catchment of approximately two million people. The FMC Sleep Centre receives ≥ 2500 referrals annually, of which 46% are for OSA [20]. As part of the triage process, all newly referred patients undergo a one-night HSAT (Remmers Sleep Recorder, Sagatech Inc.) and complete a questionnaire that explores sleep symptoms and medical history. The results of the HSAT and questionnaire are reviewed by a provincially registered respiratory therapist using a physician-approved triage protocol to ensure that there is a clinical suspicion of OSA and to assign triage urgency. The entire triage process (HSAT, questionnaire, and review) is typically completed within one month of referral, after which patients are scheduled for assessment by a sleep physician or nurse practitioner.
At the initial clinic visit, the care provider and patient establish a management plan that typically involves ambulatory PAP titration for individuals with uncomplicated OSA; PAP is usually prescribed at the initial visit and initiated within 1 week. Patients who are medically complex or with severe nocturnal hypoxemia suggesting hypoventilation may be referred for polysomnographic PAP titration before initiating therapy. Follow-up is typically delegated to alternative care providers (ACPs); at the FMC Sleep Centre, ACPs are registered respiratory therapists who have completed a three-year accredited training program in Canada and have at least five years of experience assessing and managing patients with OSA. Follow-up assessments are defined by a physician-approved protocol that complies with provincial practice regulations for registered respiratory therapists. Services include therapy education, support for patients with difficulty tolerating therapy, small adjustments to PAP to improve adherence and ordering of HSAT. Patients may be referred back to sleep physicians for management of issues outside of the ACP’s scope of practice, a model with demonstrated efficacy [21]. All sleep diagnostic test interpretations and treatment prescriptions are completed by sleep physicians. Testing is provided at no charge. Therapeutic options include lifestyle modifications, use of mandibular advancement devices and/or PAP. Positive airway pressure therapy is provided by community-based respiratory homecare providers; costs for PAP therapy are borne by the patient (out-of-pocket or through private insurance) or through government programs for individuals with low income.

Wait times for assessment at the FMC Sleep Centre vary depending on triage urgency. Patients with uncomplicated OSA typically wait between 6-12 months, while those with significant cardiopulmonary comorbidity or severe nocturnal hypoxemia are deemed urgent and are assessed within 3 months. Polysomnography, if required for more complex cases, is typically completed within 1 month.

**Eligibility Criteria:**

Patients will be included if they are ≥18 years old and have clinically significant OSA diagnosed using HSAT with a 4% oxygen desaturation index (ODI). Clinically significant OSA will be defined as an ODI ≥5/hr with excessive sleepiness (Epworth Sleepiness Scale (ESS) of ≥10) or an ODI ≥15 events/hr. Patients will be excluded if any of the following criteria are met: severe nocturnal hypoxemia on HSAT (mean SpO2 ≤85%), severe hypersomnolence (Epworth Sleepiness Scale score ≥16), safety-critical occupation, self-reported motor vehicle collision within 1 year, hypertension requiring ≥3 antihypertensive medications, hospital admission within 30 days of referral due to unstable
cardiopulmonary or cerebrovascular disease, upcoming major surgery within 6 months of triage, prior history of OSA treatment, and/or significant co-morbid sleep disorder that would interfere with CPAP acclimatization and adherence. These exclusion criteria align with clinical guidelines recommending expedited care [16]. Patients meeting these criteria are at higher risk for complications of untreated OSA, raising ethical concerns with delaying care.

**Study Procedure**

Potentially eligible patients will complete paper consents at time of HSAT appointment and eligibility will be confirmed by FMC Sleep Centre respiratory therapists at time of triage review. Participants will subsequently be randomized to either early management or usual care with a 1:1 allocation using a concealed computer-generated randomization sequence. Participants randomized to early management will be scheduled for an appointment with a sleep physician or nurse practitioner within 1 month of HSAT date whereas those randomized to usual care will be scheduled in 6 months. For feasibility, patients will be booked within 2 weeks of the desired timeframe. By virtue of the randomization and scheduling process, the participants, research associate and booking clerks will be un-blinded to allocation. Clinicians will not be informed of the study arm but will have access to time-stamped referral information routinely available in patient charts.

After initial assessment, decisions regarding additional sleep diagnostic testing and treatment will be at the discretion of the patient and sleep physician/nurse practitioner as per usual practice. Based on current practice and study eligibility criteria, it is expected that most patients will be prescribed an ambulatory PAP titration at the time of the initial assessment and will not require polysomnography. Clinical follow-up at 3 months will be delegated to ACPs; duties will comply with current policy. Patients will receive automatically generated emails at 2 weeks, 1 month and 2 months after PAP initiation to identify problems with therapy. All email responses will be reviewed by the study team and forwarded to ACPs as required.

**Data Collection:**

The timeline of data collection is outlined in Table 1. Patient demographics, symptoms, patient-reported comorbidities and medications, Epworth Sleepiness Scale score and HSAT data will be obtained at the initial visit. Nightly PAP usage data and residual OSA on therapy are recorded on PAP devices and transmitted to cloud storage operated by the manufacturer or stored on a removable chip in the device.
After 1 week and 3 months of therapy, PAP data will be obtained from cloud storage or from the patients’ provider. Each participant will complete 6 different questionnaires, including:

Epworth Sleepiness Scale (ESS) – The ESS is a validated patient-reported measure of daytime sleepiness and will be used to evaluate OSA symptom severity at baseline and 3 months [22]. The ESS includes eight questions assessing how likely a patient is to fall asleep in different scenarios on a scale of 0 to 3, with a higher score indicating more severe sleepiness.

Visit-Specific Satisfaction Instrument (VSQ-9) – Patient satisfaction is an important determinant of adherence to PAP therapy [23]. The VSQ-9 is a simple, validated nine-question tool to measure patient satisfaction during an outpatient visit [24]. It has been used in prior studies evaluating care delivery models for OSA [25, 26].

EuroQOL-5D (EQ-5D-3L) – The EQ-5D-3L is a standardized instrument used to measure general health-related quality of life. Quality of life scores are obtained by combining patient ranking of level of impairment in general health areas such as mobility and mood with an overall visual analogue scale of quality of life [27].

Sleep Apnea Quality of Life Index (SAQLI) – The SAQLI is a validated disease-specific health-related quality of life (HRQOL) questionnaire that identifies symptoms and functional impairment in five domains: daily functioning, social interactions, emotional function, symptoms, and treatment-related symptoms. The SAQLI is sensitive to changes experienced by patients and is preferred over other disease-specific HRQOL measures for OSA because it includes a domain for treatment-related effects [28, 29].

Patient Activation Measure (PAM®) – The PAM® is a validated tool to assess patient activation in self-management. The PAM® is based on four stages: believing an active patient role is important; possessing the necessary confidence and knowledge to act; taking action to maintain and improve health; and staying the course under stress [30, 31]. The PAM® score can be used to categorize patients into levels of activation that correlate with health outcomes and has been used in prior studies of interventions to improve PAP adherence [32].
Self-Efficacy Measure for Sleep Apnea (SEMSA) – The SEMSA is a validated disease-specific tool, drawn from social cognitive theory, that evaluates perceptions of risks to health, expectations of treatment outcomes and confidence to engage in health-promoting behavior. The SEMSA identifies patients at risk of PAP non-adherence and was selected to assess factors that may mediate the relationship between wait times for care and treatment adherence [33].

Additional questions exploring other aspects of the participant’s OSA history and care will be included (Appendix 1); we have previously used these questions to assess duration of OSA symptoms before seeking care, wait times for care, perceptions about wait times for OSA care and impact of OSA on work or school attendance and productivity [34, 35].

Participants will have the option of completing questionnaires electronically or on paper. Participants will be sent an emailed questionnaire link at baseline and after 3 months of therapy. Those who do not complete follow-up questionnaires will be sent automatic e-mail reminders weekly for 4 weeks. If the online questionnaire has not been completed by time of follow-up appointment, a paper copy will be provided at that visit.

Finally, we will conduct semi-structured focus groups to explore patient perspectives on wait times for OSA care, the impact of delays for care on treatment outcomes and how expedited care affects patient engagement and treatment adherence. At the end of the study, patients from each arm will be invited to participate in focus groups (Appendix 2).

Data Analysis:

Descriptive statistics will be used to report baseline characteristics. Study outcomes in the early management and usual care groups will be compared three months after PAP initiation using t-tests or Mann-Whitney U tests for analysis of continuous variables as appropriate. Chi-squared tests will be used to compare binary variables. The primary outcome will be the mean number of hours of PAP use per night in the four weeks prior to the 3-month follow-up, measured as a continuous variable.

Secondary outcomes will include: the proportion of patients who do not initiate PAP therapy; the proportion of patients using PAP therapy for at least 4 hours per night on at least 70% of nights during the four weeks prior to the 3-month follow-up [36]; change in ESS from baseline (initial clinic
visit) to 3 months after PAP initiation; change in EQ-5D-3L visual analog score from baseline to 3 months after PAP initiation; change in SAQLI from baseline to 3 months after PAP initiation; VSQ-9 total score compared between groups at baseline and after 3 months of PAP therapy; change in PAM score from baseline to 3 months after PAP initiation; change in patient activation level from baseline to 3 months after PAP initiation; SEMSA score compared between groups at baseline and after 3 months of PAP therapy; and patient perceptions about wait times for diagnosis and treatment, compared between groups.

Multiple linear mixed-effect models will be used to assess the relationship between study allocation and PAP adherence. Based on prior literature [37] and consensus of the study investigators, model covariates will include age, sex, household income, education level, baseline OSA severity, BMI, duration of symptoms prior to seeking medical attention, actual time to PAP initiation, PAP type, use of PSG for PAP titration, initial provider (physician vs. nurse practitioner), baseline sleepiness, quality of life, psychological measurements (e.g. cognitive and motivational knowledge, self-efficacy, perceived risk of OSA), PAP pressure and side effects and first week of PAP therapy use as a surrogate for early adherence [38].

Focus groups will be recorded, transcribed verbatim and coded by two study team members using the NVivo software platform. These study team members will use an inductive approach to identify themes and sub-themes from the qualitative data, first independently and then through regular meetings to achieve consensus.

**Sample Size:**

The study hypothesis is that the early management strategy will be superior to usual care with respect to the primary outcome of PAP adherence at 3 months. Based on a minimum clinically important difference of 0.5 hours/night [39], standard deviation of 1-hour, two-sided alpha 0.05 and power 0.9, a sample of 126 (63 in each arm) will be required. To account for dropouts and patients treated with non-PAP therapies, 200 patients will be recruited. Focus groups will consist of 20 participants although this may be adjusted to achieve data saturation. Current referral volume at the FMC Sleep Centre indicates that recruitment will be completed within one year.

**Ethics:**

*Research Ethics Approval:*
Ethics approval was obtained from the Conjoint Health Research Ethics Board (CHREB ID: REB20–1667) at the University of Calgary. The ethics approval process involved reviewing the study with respect to content and compliance with applicable research and safety regulations. In addition to initial approval, CHREB will review the study on an annual basis.

Consent or Assent:
Study participants will complete an informed consent form prior to initial questionnaires at the time of first visit. The form outlines the study objectives and details, including risks and benefits, and was written at a grade 9 reading level using Hemingway (www.hemingwayapp.com). Patients will be notified if they are eligible based on HSAT results and can withdraw at any time, either completely or for questionnaires only. Data contributed up to the point of withdrawal will be retained and if a participant withdraws from questionnaires only, we will collect PAP download data at 3 months.

Data Storage and Confidently:
All electronic and paper study data will be stored according to the University of Calgary’s information and security policy. Paper data will be entered into the Research Data Capture platform (REDCap). PAP adherence downloads and other patient data will be stored securely and in accordance with University of Calgary Research Ethics Board requirements. Random audits of study data will be performed at regular intervals for quality assurance purposes. Electronic study data will be maintained on secure, password-protected, and encrypted servers behind the University of Calgary firewall.

Anticipated Results, Dissemination, and Knowledge Translation.
Delays for OSA care are widespread and may lead to adverse health outcomes by prolonging exposure to untreated disease or by hindering patient engagement with therapy. This project will clarify if an early management strategy improves treatment adherence and patient reported outcomes compared to usual care that incorporates delays. This study will quantify the impact of timely management of OSA on PAP adherence and patient-reported outcomes. Although patients identify wait times for OSA care as problematic [40], there is limited research exploring whether expediting care improves OSA outcomes. Furthermore, wait time reduction strategies may have significant downstream cost and resource implications. Prior evidence in a more complex patient population suggests that shorter wait times could modify perceptions about the urgency of OSA treatment leading to greater adherence and improved outcomes [19]. To prioritize an OSA wait times reduction strategy, these
findings must be confirmed prospectively in a more generalized population of patients. The results of this study will support the development and implementation of efficient models of OSA care and inform clinical guidelines for optimal care of patients with OSA. More broadly, the findings of this study may improve the understanding of how wait time reductions impact health outcomes for other chronic diseases and inform future research and quality improvement initiatives.
Figure Legend.

Figure 1: Study Design Flow: Recruitment and Data Collection.

HSAT – home sleep apnea test; PAP – positive airway pressure. * Ambulatory PAP titration typically occurs within 1 week of clinic assessment, but patients with significant cardiopulmonary comorbidity may be referred for polysomnographic PAP titration at the discretion of the sleep physician (unlikely to be required based on eligibility criteria).
Table 1: Timeline of Data Collection

<table>
<thead>
<tr>
<th>Data Collected</th>
<th>Baseline*</th>
<th>Follow-Up**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics (age, sex, BMI, patient-reported medical comorbidity and medication use, patient-reported psychological comorbidity***, residence location by postal code and education level, household income, regular bed partner).</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Funding source for PAP (government, private insurance or out-of-pocket)</td>
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<td></td>
</tr>
<tr>
<td>Sleep study (REI, AHI, ODI, nocturnal SpO2)****</td>
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<td></td>
</tr>
<tr>
<td>Positive Airway Pressure (PAP) adherence (machine download)</td>
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<td></td>
</tr>
<tr>
<td>Epworth Sleepiness Scale (ESS)</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Visit-Specific Satisfaction Instrument (VSQ-9)</td>
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<td>X</td>
</tr>
<tr>
<td>EuroQOL-5D-3 level (EQ-5D-3L)</td>
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<td>X</td>
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<tr>
<td>Sleep Apnea Quality of Life Index (SAQLI)</td>
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<td>X</td>
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<tr>
<td>Patient Activation Measure (PAM®)</td>
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<td>X</td>
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<tr>
<td>Self-Efficacy Measure for Sleep Apnea (SEMSA)</td>
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<td>X</td>
</tr>
<tr>
<td>Focus Group</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

BMI: body mass index; REI: respiratory event index; AHI: apnea–hypopnea index; ODI: oxygen desaturation index; nocturnal SpO2: mean and nadir nocturnal oxygen saturation.

*Baseline data will be collected from consenting patients at the time of initial visit; **Follow-up data will be collected after 3 months of treatment with PAP; ***Including claustrophobia, depression and/or anxiety; ****If a patient undergoes polysomnography, OSA severity will be reported from the home sleep apnea test, and we will report the number of patients undergoing polysomnography.
Appendix 1: Additional Questions
Note: Questions will be included in the initial or follow-up surveys as indicated below.

1. How long did you wait before you decided to see a healthcare provider about your sleep? [initial]
   - < 6 months
   - 6 – 12 months
   - 1 – 3 years
   - 3 – 5 years
   - 5-10 years
   - > 10 years

2. Who was the first healthcare provider you saw about your sleep problem? [initial]
   - Primary care/family doctor or nurse
   - Dentist
   - Specialist doctor
   - Private sleep company employee
   - Other (please specify): ______________________
   - Do not know

3. How long did you wait between seeing a healthcare provider about your sleep and having a diagnostic sleep test? [initial]
   - < 1 month
   - 1 – 3 months
   - 3 – 6 months
   - 6 months – 1 year
   - > 1 year

4. The time between seeing a healthcare provider and having a diagnostic sleep test was: [initial]
   - Too short. If so, why? ________________________.
   - Acceptable.
   - Too long. If so, why? ________________________.

5. The time between the diagnostic sleep test and your first visit with a sleep specialist was: [initial]
   - Too short. If so, why? ________________________.
   - Acceptable.
   - Too long. If so, why? ________________________.

6. The time between seeing the sleep specialist and starting treatment with PAP was: [follow-up]
   - Too short. If so, why? ________________________.
7. Are you still on treatment for your sleep apnea? If not, please indicate reasons for discontinuation. [follow-up]

8. Approximately how many days of work/school did you miss in the last 3 months due to sleepiness/fatigue? [initial and follow-up]

9. Have you developed any of the following symptoms since starting CPAP? [follow-up]
   - Dry nose/mouth.
   - Nasal congestion
   - Mask leak?

10. What supports do you identify to help with your sleep apnea? [initial and follow-up]
    - Spouse/partner.
    - Close friend/family.
    - Therapist.
    - Other: _____.

11. What therapy have you used since your initial visit for your sleep apnea? [follow-up]
    - Positive airway pressure (CPAP or BiPAP) machine.
    - Dental appliance.
    - Lifestyle changes, example: weight loss, reduce alcohol.
    - No therapy.
    - Other: _____.
Appendix 2: Draft Focus Group Guide

1. Let’s begin with each introducing ourselves including your first name, the city/town you live in, and what led you to seek care for possible OSA.
   - Who was the first healthcare provider you spoke to (family doctor, specialist, other)?
     - How long did you wait before talking to that person?
     - What prompted you to seek care for possible OSA?
   - How long between talking to a healthcare provider and getting a diagnostic test?
   - How long between getting a diagnostic test and receiving a final diagnosis of OSA?
   - How long between receiving a diagnosis of OSA and starting treatment?
     - How many treatments have you tried?

2. Were there unexpected delays in any of the steps between first seeking care and getting on treatment?
   - What do you think were the factors that led to those delays?
   - What impact did those delays have on your health or wellbeing?

3. How do you feel about waiting for OSA care?
   - Does waiting for OSA care affect your motivation to use OSA treatment?
   - How would shorter wait times affect that motivation?
   - Does waiting for OSA care affect your confidence/skill in using OSA treatment?
   - How would shorter wait times affect that confidence/skill?

4. Can you describe your ideal wait time for obtaining a diagnosis of OSA? What is the ideal wait time for starting OSA treatment?
   - Can you think of any downsides to providing OSA care more quickly?
   - What would be required to provide OSA care more quickly?

5. Wrap-up
   - Is there anything else you’d like to tell us about regarding your experience with the diagnosis, treatment and ongoing management of OSA?
   - Of everything we discussed, what are the most important things for us to take away?
References:


